

cobra®























COBRA®
3-PLATE EMG
ENDOTRACHEAL TUBE

Instructions For Use



IE2-G

-Symbols used in device labeling- *Check individual device label for applicable symbols*	
Symbol	Description
	Sterile
	Manufacturer
	Use by date
	Do not reuse
	Do not resterilize
	Do not use if package is damaged
	Consult instructions for use
	Sterilizable in a steam sterilizer (autoclave) at temperature specified
	Catalogue number
	Batch code
	BF applied part
	Prescription only
	Medical device
	Keep away from rain
	CE Mark
	Upper limit of temperature
	Keep away from sunlight
	Non-Sterile
	Authorized representative in the European Community
	Unique Device Identifier

THIS IFU IS USED WITH THE FOLLOWING PRODUCT CODES OR CODE PRE-FIXES:

- NVPTKIT-C3P
- LSE3P
- LTE7003P
- NVTKIT-C3P

INTENDED USE

The Cobra® EMG Endotracheal Tube (ET tube) is intended to provide an open airway for patient ventilation while continuously monitoring EMG activity and status assessment of the nerves supplying the laryngeal musculature. This device must be used in connection with the Nerveäna® or any approved IEC 60601-1, compatible EMG monitoring system with 42802 DIN compatible connectors.

DESCRIPTION

Cobra® 3-Plate EMG Endotracheal Tubes are made from latex free* polyvinyl chloride (PVC) and are available in various sizes. Each tube has a radiopaque stripe, ventilator tube connector, and silver recording surface electrodes designed to record the activity of the vocal cord musculature when connected to an electromyographic (EMG) device. Each tube is sterilized by ethylene oxide (EO).

**not made with natural rubber latex*

CONTRAINDICATIONS

Non-reversible paralyzing agents, including anesthetic lubricants or topical sprays, may impair or reduce EMG responses rendering monitoring unreliable.

WARNINGS

- Intubation beyond 8 hours is not recommended. Replace with a standard ET tube if ventilation is needed beyond this period.
- Do not use if the ET tube delivers electrode impedance levels higher than recom-

mended by the EMG system in use.

- Be cautious that laser beams do not come in contact with the ET tube during laser surgery.
- Do not use if sterile package has been opened or is damaged.
- Do not use needles that have been tampered with or attempt to straighten bent needles. They may become weak and cause injury to the patient.
- Re-use or re-sterilization of single-use devices could result in patient morbidity and is an improper use of the device.
- This device does not prevent damage to nerves. The surgeon must rely on anatomical knowledge and experience to safely use this device.
- Product is for use by a licensed physician only.

PRECAUTIONS

- Inspect the device for defects prior to use and discard if any defects are found.
- Do not use product if the device expiration date on the label has passed.
- Avoid injury by disposing of devices in an appropriate FDA-approved sharps and/or biohazard container.
- Cuff should be inflated slowly with the minimum amount of air necessary to provide an effective tracheal seal.
- Cuff pressure and volume should be monitored regularly for any significant change. Deflation or an increase in pressure due to gas diffusion requires immediate attention.
- Do not excessively bend EMG monitoring ET tube in order to maintain electrical integrity. Check electrode integrity after insertion.
- Do not over inflate the ET tube cuff as this may damage the ET tube and cause blockage or airway damage.
- Do not remove an inflated ET tube cuff from the trachea as this may cause injury.
- When using a stylet, verify that it does not protrude from the patient end or

Murphy eye.

- Avoid insertion of a suction tube or stylet in a tube that has been distorted in any way. This has the potential to damage the ET tube and cause airway blockage.
- Do not subject a patient with implanted electronic device or ET tube to Magnetic Resonance Imaging (MRI) or another electric stimulation unless a medical specialist has first been consulted.
- Choose tube size in accordance with accepted clinical methods.
- Seat the connector firmly into the ventilator tube and verify it is secure. A swivel adapter may be used.
- Confirm breath sounds along with correct placement of tube and proper ventilation of lungs.
- Proper placement of the electrode recording area is critical. Review instructions for use prior to intubation.
- Deflate the cuff prior to repositioning the ET tube.
- False negative responses may arise from deep anesthesia, pre-existing neuropraxia, or fluid in surgical field. Poor electrode placement or dislodgement of electrode while moving patient can result in lack of contact between electrode and desired musculature and may also cause false negative responses.
- Any lubricant used on the ET tube that occludes the main lumen will impede the functionality of the device.

INSTRUCTIONS FOR USE

PLEASE READ AND FOLLOW ALL INSTRUCTIONS.

CAUTION: USE OF PARALYTICS IS A CONTRAINDICATION IN EMG NERVE MONITORING.

PREPARATION

Choose appropriate endotracheal (ET) tube size.

Prior to intubation, test cuff by slowly filling with air using a luer tip syringe.

Remove syringe from valve and check that cuff and inflation system retains air.

Reattach syringe and remove all air from cuff.

INTUBATION

1. A small amount of water-based lubricant may be applied to electrode. Do not use petroleum-based lubricants. Use of a stylet is recommended for proper placement.
2. Intubate using currently accepted medical techniques. Insert ET tube under direct vision or with a video laryngoscope. Avoid scraping electrode against sharp objects, such as patient's teeth or a laryngoscope blade.
3. Depth markings should be anterior with red wire(s) on the right and blue wire(s) on the left so that each vocal cord is touching its respective silver electrodes.
4. Note depth number on ET tube against maxillary central incisors before any further positioning of patient. Tape ET tube securely with 2 pieces of tape by wrapping each piece first around ET tube and then securing to upper lip. Do not remove tape once applied to tube. Apply additional tape if repositioning is needed.
5. Inflate cuff with minimum amount of air necessary to create an effective tracheal seal. Check pressure volume within cuff regularly to ensure seal is maintained.
6. After final positioning of patient, align ET tube in the middle of the pharynx behind the tongue. The posterior portion of ET tube should be directly opposite the central maxillary incisor gap at depth number noted after initial

- positioning.
7. Tightly secure ventilator circuit so that ET tube will not rotate or be displaced and then verify final electrode position by laryngoscopy with a #3 Miller Blade or with a video laryngoscope.
 8. Support ET tube to avoid kinking where it contacts teeth.

Tips to prevent pressure/tension induced kinking of the ET tube

- a. Adjust support arm & place breathing circuits over Tube Tree of the anesthesia machine.
- b. Place rolled drapes or an equivalent support on bridge of patient's nose under ET tube.
- c. Use a bite block to improve stability of the contact point between ET tube and incisors.
- d. Attach a Berman style oral airway or equivalent to the proximal elements of ET tube.

1-CHANNEL LEAD WIRES CONNECTION

1. Attach the red and blue electrode lead wires to the + terminal and – terminal of a single EMG recording channel. It is not necessary to utilize the red/white and blue/white wires when using the Cobra 3-Plate on a single channel EMG system.

2-CHANNEL LEAD WIRES CONNECTION

1. Attach the red and blue electrode lead wires to the + terminals of two selected channels of the EMG recording device.
2. Attach the red-white and blue-white electrode lead wires to the – terminals of the two selected channels of the EMG recording device.

GROUND ELECTRODE AND STIM RETURN PLACEMENT (included in kits)

** patient placement is suggested based on electrode type and EMG system*

a. For Nerveäna® system, apply green hydrogel to forehead. Attach green ground wire to green ground port of the EMG cable. Insert white STIM return electrode to deltoid muscle. (See figure 1)

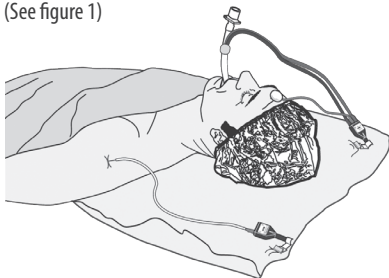


Figure 1

b. For Nerveäna® Plus and alternative EMG systems, insert white STIM return electrode to sternum and insert green EMG ground electrode just below that. (See figure 2)

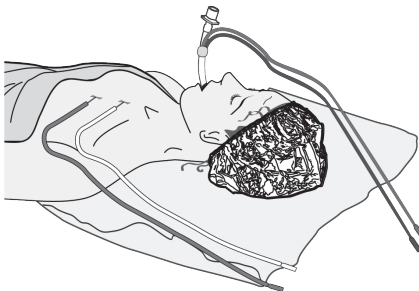


Figure 2

EXTUBATION

1. Extubate using currently accepted medical techniques.
2. Prior to extubation, deflate cuff completely with a Luer tip syringe.
3. Remove all tape. Pull out gently by ET tube; do not pull by harness.
4. Dispose of device and packaging in accordance with hospital waste standards and federal regulations.

RECOMMENDATIONS

- A bite block is recommended when using an endotracheal tube to prevent tube damage.
- Communication between the surgeon and anesthesia provider is recommended to confirm expectations for pharmacological effects on neuromuscular activity.
- Clinicians should have experience with intraoperative neurophysiologic monitoring.
- Contact Customer Service, Sales or Clinical Support for any questions concerning the care or use of this product.



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